RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1-24 were filed and are presented herein for reconsideration.

B. Objection to the Claims and Specification

(1) The claims are objected to for including blank lines. In response, it is noted that corresponding information for a biological deposit of seeds of the claimed variety will be inserted. The objection is thus believed moot and removal thereof is respectfully requested.

(2) The Action objects to claim 6 as failing to further limit claim 2. In response, Applicants note that the claim is a proper dependent form and thus the objection should be removed. Specifically, claim 6 refers back to claim 2, incorporates the limitations of the claim from which it depends, and specifies a further limitation. The claim is therefore proper and authorized under 37 C.F.R.§ 1.75(c). Removal of the objection is thus respectfully requested.

(3) The Action objects to the specification for including blank lines. In response, it is noted that corresponding information for a biological deposit of seeds of the claimed variety will be inserted in the specification. The objection is thus believed moot and removal thereof is respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects the claims under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which Applicants regard as the invention. The individual rejections and Applicants' response are set forth below

(1) The Action object to claims 10 and 18 for use of "derived." In response it is noted that there is nothing indefinite about the term because "derived" has a well known meaning in the art and further because the manner in which the plant is derived is specified in the steps of the claim itself. The term is therefore fully definite when viewed in the context of the entire claims, as is specifically required under the second paragraph of §112. Removal of the rejection is thus respectfully requested.

(2) Claim 11 is rejected for the use of "capable." In response, Applicants note that the same rejection was made and reversed in Appeal No. 2005-0396. In that case claim 20 read as follows "20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I180580, wherein a sample of the seed of the corn variety I180580 was deposited under ATCC Accession No. PTA-3224.." The Examiner ejected the claim on the same grounds as here, namely that because the claims use the term "capable" the claims do "not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed." The Board reversed, explaining that

> To address the examiner's concerns, we find it sufficient to state that if a plant has the capacity to express the claimed characteristics it meets the requirement of the claim regarding 'capable of,' notwithstanding that due to a particular phase of the life cycle the plant is not currently expressing a particular characteristic. Alternatively, if a plant is incapable of expressing the claimed characteristics at any phase of the life cycle, because it lacks, for example, the 'transcription factor' required for expression - such a plant would not meet the requirement of the claim regarding "capable of."
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> Here, we find the examiner's extremely technical criticism to be a departure from the legally correct standard of considering the claimed invention from the perspective of one possessing ordinary skill in the art. In our opinion, a person of ordinary skill in the art would understand what is claimed. *Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d

1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). We find the same to be true for the phrase 'capable of' as set forth in claims 17 and 20.

Decision at p. 12.

The issue has therefore been resolved by the Board on identical facts and circumstances. Removal of the rejection is thus respectfully requested.

(3) The Action asserts that "mappable genetic loci" is indefinite in claims 19 and 23. In response, Applicants note that contrary to the allegation made, the term does have a well know meaning in the art. Specifically, it is known that the corn genome is made up of a series of loci which are mappable, for example, using well known genetic marker technology. Such loci are therefore mappable genetic loci and this is understood in the art, particular when taken in the context of the entire claim. The claim is therefore fully definite as written and removal of the rejection is thus respectfully requested.

D. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

(1) The Action rejects claims 1-24 under 35 U.S.C. §112, first paragraph, for lack of a seed deposit.

In response, Applicant notes that a deposit of 2,500 seeds of the claimed variety will be made with the ATCC in accordance with all of the relevant rules. A declaration certifying that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809 will be provided and the claims amended to recite the corresponding accession number. The specification will also be amended to include the accession number of the deposit and the date of deposit.

(2) The Action rejects claims 15-22 as not enabled. The claims are directed to corn plants of the claimed variety which comprise a locus conversion or a nuclear or

cytoplasmic gene conferring male sterility. The Action alleges that no guidance has been provided for creation of such plants and asserts non-enablement because absolute purity of backcrossed progeny may not be retained. However, this ignores the working example in the specification describing a conversion that was made with a proprietary corn variety. This example gives the breeding history of the conversion that was made, including a description of seven backcrosses. The example describes exactly the type of process one of skill in the art could use to prepare conversions of the instant variety. The specification provides in great detail further guidance for creation of converted plants at pages 29-33. The techniques recited are also all well known in the art (*e.g.*, Poehlman *et al.*, 1995; Fehr, 1987; Sprague and Dudley, 1988).

With regard to creation of male sterile plants, this is also a technique that has been well-known for decades. This is evidenced by the numerous issued patents for creation of male sterile plants (see U.S. Patent No. 3,861,709; U.S. Patent No. 3,710,511; U.S. Patent No. 4,654,465; U.S. Patent No 5,625,132; U.S. Patent No. 4,727,219; U.S. Patent No. 5,530,191; U.S. Patent No. 5,689,041; U.S. Patent No. 5,741,684; and U.S. Patent No. 5,684,242, incorporated by reference).

Corn breeding is extremely advanced and well known in the art. This is due in large part to the fact that corn is one of the world's major food crops and largest seed crops. As explained in the specification, North American farmers alone plant ***tens of millions of acres*** of corn at the present time and there are ***extensive national and international commercial corn breeding*** programs. In sum, no basis has been provided to conclude why anything other than routine experimentation using these well known techniques would be required. Removal of the rejection is thus respectfully requested.

E. Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Written Description

The Action rejects claims 15-24 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey that Applicants were in possession of the claimed invention. For example, it is asserted that a plant of the claimed variety comprising a male sterility gene or locus conversion, F1 hybrid progeny of the claimed variety and methods of plant breeding comprising use of the claimed variety as starting material lack written description.

In response Applicants initially note that all of the rejections made have specifically been considered and reversed by the Board of Patent Appeals on the same subject matter presented in the current case. The rejections must be removed on the same basis as provided by the Board, as explained below. For example, in Appeal No. 2005-0396, discussed above, the Board of Patent Appeals decided five other substantially similar appeals on March 31, 2005 brought by the current Real Party in Interest: Appeal Nos: 2004-1503 (Ser No. 09/606,808), 2004-1506 (Ser. No. 09/788,334), 2004-1968 (Ser. No. 10/000,311), 2004-2317 (Ser. No. 09/771,938), and 2004-2343 (Ser. No. 09/772,520) (collectively "the corn variety appeals"). The issues decided in these cases were the same as those raised by the current case.

In the corn variety appeals, for example, rejections were raised based on an alleged lack of written description for F1 hybrid plants. Specifically, it was alleged that the F1 hybrid plants only have as half of their genome the genome of the parent plant of interest and the remaining portion was not described, and thus written description is

lacking, despite the fact that no particular second hybrid plant is required by the method. *See* Board Decision at p. 17.

The Board rejected this reasoning, noting that, as here, the claims require no particular second parent of the F1 hybrid and the Examiner had already acknowledged written description for the variety of interest. The Board also specifically disagreed with the Examiner's assertion that the fact that any hybrid plant will inherit half of its alleles from the parent variety does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants. *Id.* The Board thus held that "there can be no doubt that the specification provides and adequate written description of this corn variety." *Id.* at p. 18. As explained by the Board, the purpose of the written description requirement is to "ensure that the right of the scope to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Id.*

Here, as in the corn variety appeals, the claimed F1 hybrid plants must have the admittedly described variety of interest as one parent, and thus the claims do not overreach the scope of the inventor's contribution and are fully described. The Board rejected the notion that an Applicant must define every possible second parent plant of a hybrid cross and the morphological characteristics of the progeny to provide written description for claimed hybrid plants. In particular, the Board stated that it "disagree[d] with the examiner's conclusion (id.) that '[t]he fact that any hybrid plant will inherit half of its alleles from [the variety of interest] then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants." *Id.*

Methods of plant breeding are similarly described. Essentially identical written description rejections were raised by the Examiner in Appeal No. 2005-0396 of claims drawn to a method of breeding corn plants comprising use of the variety of interest as starting material. In the appeal the Examiner argued that written description is lacking because the intermediate plants at each step of the method allegedly must be described to satisfy written description and that such plants had not been defined, regardless of the fact that the only starting material required by the claims was the variety of interest, which was admittedly fully defined. *See* p. 12-15. The Board rejected this reasoning, noting that, given the acknowledgement of written description for the variety of interest, appellants were also in possession of a method of using that plant for crossing with any other plant to produce an inbred plant as set forth in the claims. See Board Decision at p. 24 ("Therefore, in our opinion, there can be no doubt that appellant was in possession of a plant of the corn variety 1180580, in addition to a method of using that plant to cross with any other corn plant to produce an inbred corn plant as set forth in appellant's claim 31"). The Board thus concluded that appellant established with reasonable clarity that they were in possession of the invention. In the context of methods of introducing transgenes, the Board noted that no evidence was provided to support the rejections or inadequacy of written description for the claims. The Board thus reversed the written description rejections.

The same issues have been presented here on claims of the same substantive scope. As the Board has already decided all of the rejections made here in Applicants favor in the corn variety appeals, removal of the rejection is respectfully requested.

1. F1 Hybrid Plants Are Fully Described

The rejected claims are directed to F1 hybrid plants and seeds produced with the claimed variety as one parent. Applicants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history in the specification, corn plant I029010 is an inbred corn plant. All of the claimed hybrid plants having I029010 as a parent will therefore contain a copy of the same genome as corn plant I029010. That is, because I029010 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I029010, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant I029010 is described in the specification by way of the proffered deposit of seed of corn plant I029010 with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one*

can do with a fully described genus, visualize or recognize the identity of the members of the genus" (emphasis added)). Here, all of the members of the claimed genus of hybrids having I029010 as one parent share the structural feature of having the genetic complement of I029010. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant I029010 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Applicants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals more than 300 utility patents issued on different corn varieties issued prior to the filing date of the current application. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn variety I029010 as one parent, and each of these would share the genetic complement of I029010.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In*

re Buchner, 929 F.2d 660, 661 (Fed. Cir. 1991). As ***any*** second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Applicants cannot be said to have not been in possession of the second parent plant. Removal of the rejection is thus respectfully requested.

2. Methods of Plant Breeding Are Fully Described

The Action rejects claims covering methods of plant breeding that comprise using variety I029010 as starting material as lacking written description. For example, it is asserted that plants created at any intermediate or penultimate step are not described by specific structure. However, what is required to meet the written description requirement is that an Applicant show that he or she was in possession of the ***claimed invention***. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Here, a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products of the steps. The starting materials for the process must also be provided, otherwise the process could not be completed. However, the only starting materials required are corn variety I029010, which the Examiner does not allege to have not been described, and ***any*** second corn plant. As set forth above, corn plants were well known, and this has also therefore been fully described.

With respect to the steps, these have been fully set forth in the claim. No essential steps have been shown to be absent. All that is required to complete the claimed method is to cross the corn variety I029010 or a product that is produced by any preceding step according to the steps given. All of the starting materials for any step within the method are either (1) corn variety I029010, (2) any second corn plant, or (3) a corn plant that is